CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION
PUBLIC REPORT 2003-8

Boscalid

Tracking ID 190602 N

DESCRIPTION OF ACTION

BASF Corporation submitted an application seeking a California registration of Pristine® Fungicide (EPA Reg. No. 7969-1999) to control certain plant diseases on various fruit, vegetable and orchard crops. Pristine® Fungicide is a mixture of pyraclostrobin, and the new active ingredient, boscalid.

The Department of Pesticide Regulation (DPR) evaluated the product label and scientific data supporting registration of the product and found them to be acceptable. The acute health risks from exposure to boscalid are minimal due in part to its low mammalian toxicity. The precautionary and first aid statements on the product label, as well as label directions requiring personal protective equipment (PPE) and other protective measures adequately mitigate potential health risks to persons who may come in contact with the pesticide. DPR does not expect significant adverse environmental impacts to result from registration of this product.

DPR accepted BASF Corporation's application for registration of Pristine® Fungicide concurrently with their application to the United States Environmental Protection Agency (U.S. EPA) for federal registration of this product. Pristine® Fungicide was registered by the U.S. EPA on July 23, 2003. The Reduced Risk Committee at U.S. EPA granted "reduced risk status" to boscalid for the uses on the current label.

BACKGROUND

Brand name:	Pristine® Fungicide
Registrant:	BASF Corporation
Common name:	Boscalid
Chemical name:	3-pyridinecarboxamide,2-chloro-N-(4'-chloro(1,1'-biphenyl)-2-yl)
Common name:	Pyraclostrobin
Chemical name:	(carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester)
Uses:	To control diseases in various fruit, vegetable, and orchard crops
Pests controlled:	Blossom blight, brown rot, Downey mildew, powdery mildew, Alternaria leaf spot
Type of registration:	Conditional for one year

Pristine® Fungicide is formulated as a water dispersible granule with 12.8% pyraclostrobin and 25.2% boscalid. As a combination of two fungicides with different modes of action, Pristine® Fungicide can provide broad-spectrum control of several different plant diseases on a variety of crops. It can be used as a protectant because it inhibits fungal spore germination. In addition, it can be used as a curative, because it inhibits mycelial growth and sporulation of the fungus on

the leaf surface. Pristine® Fungicide should be used following the comprehensive resistance management program outlined on the label. This program includes applying Pristine® Fungicide in combination with other fungicides and/or alternating Pristine® Fungicide applications with applications of other fungicides with different modes of action. The label instructions also limit the number of sequential Pristine® Fungicide applications that can be made on a particular crop.

Pristine® Fungicide can be applied to berries, bulb vegetables, carrots, grapes, pistachios, stone fruits, strawberries, and tree nuts. Application rates range from 10.5-23 oz. per acre, depending on the crop, with a maximum of six applications per growing season. The product can be applied as a broadcast treatment with ground boom or aerial equipment, or with a sprinkler irrigation system. The minimum time interval between the last application and harvest ranges from 0-14 days. There is a minimum 14-day waiting period after the last Pristine® Fungicide application before crops not listed on the label can be planted.

SCIENTIFIC REVIEW

A. Chemistry

1. Product Chemistry: DPR evaluated the submitted chemistry studies for the formulated product Pristine® Fungicide and summarized the results in the following table:

Table I. Physical and Chemical Properties of Pristine® Fungicide

Properties	Values
Physical state	Solid
Bulk density	0.615 Kg/L g/cm^3
Nominal concentration	25.2% Boscalid 12.8% Pyraclostrobin
Certified limits	26.0, 24.4% Boscalid 13.2, 12.4% Pyraclostrobin
Analytical technique/detector	HPLC
Vapor pressure (20?C)*	7 X 10-7 Pa
Water solubility (pH=6 and 20?C)*	4.64 mg/L
Octanol/water partition coefficient (20?C)*	Log Kow = 2.95
Storage stability	Not submitted

* These properties were derived using technical boscalid as the test substance.

2. Residues in Food and Animal Feed: The submitted residue studies support the harvest and use limitations for the crops listed on the Pristine® Fungicide label. The proposed tolerances for the crops listed on the product label include the combined food residues of boscalid, pyraclostrobin and their metabolites are not likely to exceed the proposed tolerance levels.

3. Environmental Fate: The boscalid environmental fate studies which included: soil adsorption/desorption, hydrolysis, photolysis (aqueous and soil), aerobic and anaerobic soil metabolism, and terrestrial field dissipation have been found to be satisfactory. Boscalid is considered to be nonvolatile (Vapor pressure is $7X10^{-7}$ Pa at 20?C), and it is stable to

hydrolysis, and aqueous and soil photolysis. Koc values indicate that boscalid has low mobility in the different soil types used in the study. In some of the terrestrial field dissipation studies, residues were found in the top 0-18" of soil. However, no boscalid residues were found below the top 18" of soil in any study.

DPR has developed a set of physical-chemical properties (specific numerical values) in response to the Pesticide Contamination Prevention Act (Food and Agricultural Code, section 13144) that may be used to predict the potential of a chemical to leach to ground water. The specific numerical values for boscalid indicate a potential to move off site in water through leaching or runoff. However, based on information from the field dissipation studies submitted by BASF, some of which were conducted under exaggerated residue-leaching scenarios, movement of the test product and its degradates was limited to a soil depth of 12-18 inches in the turf and cropping plots. Based on computer modeling, residues of the test product below 10 feet were estimated at concentrations greatly below the limit of quantification, even when modeled under inefficient irrigation and low soil organic matter conditions. The modeling scenario used could be conservative because the processes of leaf interception or plant root uptake of the product were not included in the modeling. Based on the data and modeling information, DPR concluded that boscalid is unlikely to present a serious threat to California groundwater when used according to the Pristine® Fungicide label directions.

B. Toxicology

BASF Corporation submitted adequate toxicology studies to conduct a complete toxicological evaluation of Pristine® Fungicide. DPR evaluated the submitted data to ascertain the potential for adverse health effects. The acute toxicity parameters for Pristine® Fungicide are summarized in Table II:

Table II. Acute Toxicity of Pristine® Fungicide

Type of Study	Acute Toxicity Values	Acute Toxicity Category
Acute oral	LD_{50} >1050 mg/kg	III
Acute dermal	LD_{50} >2000 mg/kg	III
Acute inhalation	LC_{50} >5.4 mg/l	IV
Primary eye irritation	N/A	III
Primary dermal irritation	N/A	IV
Dermal sensitization	N/A	Not a dermal sensitizer
Signal word	N/A	CAUTION

N/A-Not applicable.

DPR's evaluation of the acute toxicity studies indicates that Pristine® Fungicide is low in mammalian toxicity. The precautionary language on the product label adequately identifies the acute toxicity hazards noted in the studies.

DPR found the submitted toxicology studies adequate to satisfy the data requirements of the Birth Defects Prevention Act (Food and Agricultural section 13121 et. al.). The rat

oncogenicity study indicated a possible adverse effect on the thyroid gland. At this time, boscalid has not been prioritized by DPR for risk assessment. DPR prioritizes pesticide active ingredients for risk assessment based on the nature of the potential adverse health effects, number of potential adverse health effects, number of species affected, NOELs, potential for human exposure, use patterns, and similar factors. Based on these criteria, pesticides with the greatest potential for health problems are placed in high priority, with other chemicals being place in moderate or low priority. The purpose of the risk assessment will be to appraise the potential for boscalid to cause adverse health effects in humans if exposed to the pesticide as the result of a legal use. The potential for exposure from eating food crops treated with boscalid will also be evaluated during the risk assessment. Further toxicity information is available in DPR's Summary of Toxicology Data for boscalid, available on DPR public website at http://www.cdpr.ca.gov/docs/toxsums/pdfs/5790.pdf

C. Health & Safety

An evaluation of the medical management information on the Pristine® Fungicide label and the acute toxicity studies results indicate that the product label bears all of the required statements and warnings regarding safety to handlers and other persons who may be exposed to the pesticide. The product label bears an adequate first aid statement. In addition, the product label requires persons handling and applying Pristine® Fungicide to wear long-sleeved shirt and long pants, chemical-resistant gloves, and shoes plus socks. Workers wearing only work clothing are not allowed to enter a treated field until 12 hours after an application for all crops uses, except berries and grapes which require a 24-hour waiting period. Persons entering a treated area before the 12-hour reentry interval has elapsed must wear coveralls, chemical-resistant gloves, and shoes plus socks if they are going to contact treated plants, soil or water.

D. Fish & Wildlife

The registrant submitted fish and wildlife toxicity studies, including studies on bobwhite quail, mallard duck, bluegill sunfish, rainbow trout, sheepshead minnow, Daphnia magna (water fleas), mysid shrimp, and oysters. The submitted data are adequate to characterize the toxicity to wildlife and aquatic animals from environmental exposure. Table IV summarizes the results of these studies.

Table IV. Summary of Toxicity Studies for Wildlife

Test Animal	Type of Study	Acute Toxicity Value[a]	Relative Toxicity
Bobwhite quail	Single acute oral dose	>2000 mg/kg (LD_{50})	Relatively non-toxic
Mallard duck	Feeding study (3 days)	>5000 ppm (LC_{50})	Relatively non-toxic
Bobwhite quail	Feeding study (3 days)	>5000 ppm (LC_{50})	Relatively non-toxic
Bluegill sunfish	Water exposure (96 hrs.)	>4.0 mg a.i./l (LC_{50})	Moderately toxic
Rainbow trout	Water exposure (96 hrs.)	2.7 mg a.i./l (LC_{50})	Moderately toxic
Sheepshead minnow	Water exposure (96 hrs.)	>3.86 mg a.i./l (LC_{50})	Moderately toxic
Daphnia magna	Water exposure (48 hrs.)	5.33 mg a.i./l (EC_{50})	Moderately toxic
Mysid shrimp	Water exposure (96 hrs.)	>3.81 mg a.i./l (LC_{50})	Moderately toxic
Oyster	Water exposure (96 hrs.)	1.66 mg a.i./l (EC_{50})	Moderately toxic

Values expressed as: a. LD_{50}= lethal dose that will kill 50% of test population, and b. LC_{50}= lethal environmental concentration that will kill 50% of test population.

The data indicate that boscalid is relatively non-toxic to terrestrial wildlife, but moderately toxic to freshwater fish and aquatic invertebrates. Label directions bear a warning indicating that the product is toxic to fish and aquatic organisms, and prohibit application of the product directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark.

Based on the submitted data, registered uses, label rates, and use restrictions for Pristine® Fungicide, DPR does not expect toxic concentrations to occur in aquatic environments from use of the product in accordance with label directions.

E. Efficacy & Phytoxicity

Submitted data indicate that Pristine® Fungicide provides control of various diseases on the berry group, bulb vegetables, carrots, grapes, pistachios, stone fruits, strawberries, and tree nuts. The data submitted report some phytotoxic injury on certain varieties of grapes (*vitis labrusca*) when Pristine® Fungicide is applied alone or as a tank mix with Omite™. The Pristine® Fungicide label specifically prohibits use on the sensitive grape varieties Concord, Worden, and Fredonia. In addition, the label advises that before using any tank mix, the user should test the combination on a small portion of the crop to be treated, to ensure that a phytotoxic response will not occur as result of application.

ALTERNATIVES

Boscalid is a new pesticide belonging to the class of oxathiin fungicides, also known as carboxamide, carboxin or (carbox) anilide fungicides. U.S. EPA has designated the proposed uses of boscalid as "reduced risk." Boscalid works by inhibiting mitrochondial respiration and subsequent production of ATP in fungal cells. Boscalid has a new mode of action and is effective against pathogens resistant to other fungicides, including those resistant to sterol inhibitors, dicarboximides, benzimidazoles, anilinopyrimidines, phenylamides and strobilurins.

Repeated use of the same fungicide or fungicides with similar modes of action can result in the failure to control plant pathogenic fungi, allowing them to reproduce and generate resistant fungal populations. The registration of boscalid provides an alternative fungicide that can be used in resistance management programs with other fungicides that have other alternative modes of action. Boscalid has not exhibited any known cross-resistance to sterol-inhibitor, dicarboximide, benzimidazole, anilinopyridine or phenylamide type fungicides. However, cross-resistance has been observed in plant pathogenic fungi that have been exposed to certain strobilurin fungicides, like azoxystrobin and trifloxystrobin.

CONCLUSION

DPR evaluated the product label and scientific data submitted to support the registration of Pristine® Fungicide and found them acceptable to support registration. The acute health risks to humans from exposure to boscalid are minimal due, in part, to its low mammalian toxicity. The precautionary and first aid statements on the product label, as well as the required PPE and other protective measures mitigate potential health risks to persons who may be exposed to the pesticide. If, after the risk assessment, DPR determines that exposure to boscalid may result in unacceptable margins of exposure, further restrictions will be placed on the use of boscalid at that time. Submitted data also indicate that no significant adverse environmental impacts are expected to occur from the use of Pristine® Fungicide, and that, when used in accordance with label directions, the product will be effective for its intended use.

DPR is granting a one-year conditional registration for Pristine® Fungicide. The registrant is required to conduct and submit to DPR the results of a one-year storage stability study conducted under warehouse conditions with the pesticide stored in commercial packaging.